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10/541,082

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20350 7590 06/27/2008  
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EXAMINER

HENRY, MICHAEL C

ART UNIT

PAPER NUMBER

1623

MAIL DATE

DELIVERY MODE

06/27/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |                                     |  |
|------------------------------|--------------------------------------|-------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/541,082 | <b>Applicant(s)</b><br>ZHANG ET AL. |  |
|                              | <b>Examiner</b><br>MICHAEL C. HENRY  | <b>Art Unit</b><br>1623             |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 June 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-5, 8, 9, 12, 13 and 17-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 8, 9, 12, 13, 17-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 06/06/08 has been entered.

The following office action is a responsive to the Amendment filed, 06/06/08.

The amendment filed 06/06/08 affects the application, 10/541,082 as follows:

1. Claims 1-5, 8, 9, 12, 13 have been amended. Claims 6, 7, 10, 11, 14-16 have been canceled. New Claims 17-20 have been added. Applicants' amendment has overcome the rejections made under 35 U.S.C. 101, 112 first and second paragraphs and under 35 U.S.C. 103(a). Consequently, the said rejection are withdrawn.

However, a new ground(s) is made herein.

2. The responsive to applicants' amendments is contained herein below.

Claims 1-5, 8, 9, 12, 13, 17-20 are pending in the application

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Wu et al. (*Planta medica* (1996 Aug) Vol. 62, No. 4, pp. 317-21).

Claim 1 is drawn to a method for improving memory performance in an animal, the method comprising: administering a therapeutically effective dose of a derivative of a succinate ester of a given general formula (I), or a stereo-isomer or a pharmaceutically acceptable salt thereof.

Wu et al. disclose applicant's method for improving memory performance (memory and learning) in an animal (rat), the method comprising: administering an effective dose of a composition of a derivative of a succinate ester of the given general formula (I) to an animal (see abstract). Wu et al.'s composition which comprises the derivative of the succinate ester (i.e., the active constituent(s)) of the given general formula (I) is referred to as rhizome of *Gastrodia elata* Blume (Orchidaceae) (abbreviated GE) (see abstract).

It should be noted that it is well known that the derivative of the succinate ester(s) of a given general formula (I) is present in the said *Gastrodia elata* Blume (GE). In fact, applicant acknowledges that the said derivative(s) of the succinate ester(s) of the given general formula (I) (active constituents or ingredients) are known to be present in *Gastrodia elata* (GE) of Orchidaceous plants (see page 9, last paragraph to page 10, end of 1<sup>st</sup> paragraph of applicant's specification). Also, it should be noted that Wu et al.'s method inherently improves memory performance in a animal, as claimed herein since Wu et al.'s method step(s) are same as the instant method steps, administering the same compound(s) or composition in the same amount to the same or similar animal or patient. See *Ex parte Novitski*, 26 USPQ 2d 1389, 1391 (Bd. Pat. App. & Int. 1993). Note that even the claiming of a new use, new function or unknown property

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which is inherently present in the prior art does not make the claim patentable. See *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also *Eli Lilly and Co. v. Barr Laboratories Inc.* 251 F3d. 955; 58 USPQ2d 1869-1881 (Fed. Cir. 2001) with regard to inherency as it related to the claimed invention herein.

Claims 2-5 which are drawn to the said method wherein the compounds are specific compounds of the given general formula (I) and wherein the animal has specific disorders or conditions including learning or memory obstacle, are also encompassed by this rejection since Wu et al.'s compounds or compositions are the same as applicant's and Wu et al. also treat the same learning or memory condition as applicant (see abstract).

Claims 1-5 are rejected under 35 U.S.C. 102(a) as being anticipated by Li et al. (Zhongguo Gonggong Weisheng (2002), 18 (3), 284-286).

Claim 1 is drawn to a method for improving memory performance in an animal, the method comprising: administering a therapeutically effective dose of a derivative of a succinate ester of a given general formula (I), or a stereo-isomer or a pharmaceutically acceptable salt thereof.

Li et al. disclose applicant's method for improving memory performance (memory and learning) in an animal (rat), the method comprising: administering an effective dose of a composition of a derivative of a succinate ester of the given general formula (I) to an animal (see abstract). Li et al.'s composition which comprises the derivative of the succinate ester (i.e., the active constituent(s)) of the given general formula (I) is referred to as *Gastrodia elata* Blume (GTEB) (see abstract).

It should be noted that it is well known that the derivative of the succinate ester(s) of a given general formula (I) is present in the said *Gastrodia elata* Blume (GTEB). In fact, applicant acknowledges that the said derivative s) of the succinate ester(s) of the given general formula (I) (active constituents or ingredients) are known to be present in *Gastrodia elata* (GTEB) of Orchidaceous plants (see page 9, last paragraph to page 10, end of 1<sup>st</sup> paragraph of applicant's specification). Also, it should be noted that Li et al.'s method inherently improves memory performance in a animal, as claimed herein since Li et al.'s method steps are same as the instant method step(s), administering the same compound(s) or composition in the same amount to the same or similar animal or patient. See *Ex parte Novitski*, 26 USPQ 2d 1389, 1391 (Bd. Pat. App. & Int. 1993). Note that even the claiming of a new use, new function or unknown property which is inherently present in the prior art does not make the claim patentable. See *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also *Eli Lilly and Co. v. Barr Laboratories Inc.* 251 F3d. 955; 58 USPQ2d 1869-1881 (Fed. Cir. 2001) with regard to inherency as it related to the claimed invention herein.

Claims 2-5 which are drawn to the said method wherein the compounds are specific compounds of the given general formula (I) and wherein the animal has specific disorders or conditions including learning or memory obstacle, are also encompassed by this rejection since Li et al.'s compounds or compositions are the same as applicant's and Li et al. also treat the same learning or memory condition as applicant (see abstract).

***Claim Rejections - 35 USC § 103***

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 8, 9, 12, 13, 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wu et al. (Planta medica (1996 Aug) Vol. 62, No. 4, pp. 317-21) in view of Huang et al. (Yaoxue Xuebao (2002), Vol. 37, No. 3, pages 199-203).

The same method of Wu et al. has been discussed in the 102 rejection above (see abstract).

The difference between applicant's claimed method and the method taught by Wu et al. is the composition or extract used as the extract of *Coeloglossum viride* (L.) Hartm. var. *bracteatum* (Willd.).

Huang et al. disclose applicant's pharmaceutical composition, comprising an extract (of *Coeloglossum viride* (L.) Hartm. var. *bracteatum* (Willd.) Richter) and a pharmaceutically acceptable carrier (ethanol) in the form of an injectable solution (see abstract). Furthermore, Huang et al. disclose that the extract contains compounds which includes dactylorhin B, loroglossin, dactylorhin A, militarine, coelovirin A (I), gastrodin, thymidine, and quercetin-3,7-di-O- $\beta$ -D-glucopyranoside. That is, Huang et al.'s composition also contains the same active ingredient (gastrodin) that is contained in Wu et al.'s composition which Wu et al. use to treat or improve and learning in the same animal.

It is also known that *Coeloglossum viride* (L.) Hartm. var. *bracteatum* (Willd.) and Gastrodia belong to the same Orchidaceous plants' family as admitted by Applicants (see page 9, last paragraph to page 10, end of 1<sup>st</sup> paragraph of applicant's specification).

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made, in view of Wu et al. and Huang et al., to use Wu et al.'s method to improve memory performance (memory and learning) in an animal comprising: administering an effective dose of Huang et al.'s extract of *Coeloglossum viride* (L.) Hartm. var. *bracteatum* (Willd.) Richter, which comprises the compound gastrodin that Huang et al. disclose to have the same utility of treating or improving said memory and learning in said animal, depending on factors such as the type and severity of the condition treated, the type of animal treated and the intended route or means of administration.

One having ordinary skill in the art would have been motivated, in view of Wu et al. and Huang et al., to use Wu et al.'s method to improve memory performance (memory and learning) in an animal comprising: administering an effective dose of Huang et al.'s extract of *Coeloglossum viride* (L.) Hartm. var. *bracteatum* (Willd.) Richter, which comprises the compound gastrodin that Huang et al. disclose to have the same utility of treating or improving said memory and learning in said animal, depending on factors such as the type and severity of the condition treated, the type of animal treated and the intended route or means of administration. It should be noted that applicant's claim to foreign priority over China 02159342.6 (12/21/2002) has not been perfected, since an English translation of the said foreign priority document is not filed.

#### ***Response to Arguments***



Applicant's arguments with respect to claims 1-5, 8, 9, 12, 13, 17-20 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8.30am-5pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael C. Henry

June 20, 2008.

/Shaojia Anna Jiang, Ph.D./  
Supervisory Patent Examiner, Art Unit 1623